

Appl. No. 10/813,483

Patent Docket #P2026R1

Response dated January 5, 2005

Response to Restriction Requirement mailed on December 6, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of the Claims:

1 (currently amended). A stable, liquid formulation of low turbidity comprising (a) a ~~protein or an~~ antibody in an amount of 100 to 260 mg/ml, (b) arginine-HCl in an amount of 50 to 200 mM, (c) histidine in an amount of 10 to 100 mM, (d) polysorbate in an amount of 0.01 to 0.1%, where the formulation further has a pH ranging from 5.5 to 7.0, a kinematic viscosity of about 50 cs or less and osmolarity ranging from 200 mOsm/kg to 450 mOsm/kg.

2 (original). The formulation of Claim 1, wherein the concentration of protein or antibody ranges from 120 mg/ml to 260 mg/ml.

3 (original). The formulation of Claim 1, wherein the concentration of protein or antibody ranges from 150 mg/ml to 260 mg/ml.

4 (original). The formulation of Claim 1, wherein the concentration of protein or antibody ranges from 180 mg/ml to 260 mg/ml.

5 (original). The formulation of Claim 1, wherein the concentration of protein or antibody ranges from 200 mg/ml to 260 mg/ml.

6 (original). The formulation of Claim 1, wherein the concentration of protein or antibody is about 150 mg/ml.

7 (original). The formulation of Claim 1, wherein the osmolarity ranges from 250 mOsm/kg to 350 mOsm/kg.

8 (original). The formulation of Claim 1, wherein the concentration of arginine-HCl ranges from 100 mg/ml to 200 mg/ml.

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9 (original). A stable, liquid formulation of low turbidity comprising (a) an anti-IgE monoclonal antibody in an amount of 100 to 260 mg/ml, (b) arginine-HCl in an amount of 50 to 200 mM, (c) histidine in an amount of 10 to 100 mM, (d) polysorbate in an amount of 0.01 to 0.1%, where the formulation further has a pH ranging from 5.5 to 7.0, a kinematic viscosity of about 50 cs or less and osmolarity ranging from 200 mOsm/kg to 450 mOsm/kg.

10 (currently amended). The formulation of Claim 4, wherein the concentration of protein or antibody ranges from 120 mg/ml to 260 mg/ml.

11 (currently amended). The formulation of Claim 4, wherein the concentration of protein or antibody ranges from 150 mg/ml to 260 mg/ml.

12 (currently amended). The formulation of Claim 4, wherein the concentration of protein or antibody ranges from 180 mg/ml to 260 mg/ml.

13 (currently amended). The formulation of Claim 4, wherein the concentration of protein or antibody ranges from 200 mg/ml to 260 mg/ml.

14 (currently amended). The formulation of Claim 4, wherein the concentration of protein or antibody is about 150 mg/ml.

15 (currently amended). The formulation of Claim 4, wherein the osmolarity ranges from 250 mOsm/kg to 350 mOsm/kg.

16 (currently amended). The formulation of Claim 4, where the anti-IgE antibody is selected from the group consisting of rhuMAbE25, rhuMAbE26 and Hu-901.

17 (currently amended). The formulation of Claim 4, wherein the anti-IgE antibody is rhuMAbE25.

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18 (currently amended). The formulation of Claim 4 16, wherein the anti-IgE antibody is rhuMAbE26.

19 (currently amended). The formulation of Claim 4 16, wherein the anti-IgE antibody is Hu-901.

20 (original). A stable, liquid formulation of low turbidity comprising (a) an anti-IgE antibody in an amount of about 150 mg/ml, (b) arginine-HCl in an amount of 200 mM, (c) histidine in an amount of 20 mM, (d) polysorbate in an amount of 0.02%, where the formulation further has a pH of 6.0.

21 (original). The formulation of Claim 20, wherein the anti-IgE antibody is E25.

22 (original). An article of manufacture comprising a container enclosing the formulation of Claim 1.

23 (original). The article of manufacture of Claim 22, wherein the container is a syringe.

24 (original). The article of manufacture of Claim 23, wherein the syringe is further contained within an injection device.

25 (original). The article of manufacture of Claim 24, wherein the injection device is an auto-injector.

26 (original). The formulation of Claim 1, wherein said formulation is reconstituted.

27 (original). The formulation of Claim 26, wherein the protein or antibody concentration in said reconstituted formulation is about 2-40 times greater than the concentration prior to lyophilization.

28 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20.

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29 (withdrawn). The method of Claim 28, wherein the IgE-mediated disorder is selected from the group consisting of allergic rhinitis, asthma, allergic asthma, non-allergic asthma, atopic dermatitis and gastroenteropathy.

30 (withdrawn). The method of Claim 28, wherein the IgE-mediated disorder is allergic rhinitis.

31 (withdrawn). The method of Claim 28, wherein the IgE-mediated disorder is allergic asthma.

32 (withdrawn). The method of Claim 28, wherein the IgE-mediated disorder is asthma.

33 (withdrawn). The method of Claim 28, wherein the IgE-mediated disorder is atopic dermatitis.

34 (withdrawn). The method of Claim 28, wherein the IgE-mediated disorder is selected from the group consisting of hypersensitivity, allergic bronchopulmonary aspergillosis, parasitic diseases, interstitial cystitis, hyper-IgE syndrome, ataxia-telangiectasia, Wiskott-Akdrich syndrome, thymic aplasia, IgE myeloma and graft-versus-host reaction.

35 (withdrawn). The method of Claim 28 wherein the IgE-mediated disorder is hypersensitivity.

36 (withdrawn). The method of Claim 35, wherein the hypersensitivity disorder is selected from the group consisting of anaphylaxis, urticaria and food allergy.

37 (withdrawn). The method of Claim 36, wherein hypersensitivity disorder is food allergy.

38 (withdrawn). The method of Claim 37, wherein the food allergy results from exposure to a legume.

39 (withdrawn). The method of Claim 38, wherein the legume is a peanut.

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40 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with an antihistamine.

41 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with the administration of an antihistamine.

42 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with a bronchodilator.

43 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with the administration of a bronchodilator.

44 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with a glucocorticoid.

45 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with the administration of a glucocorticoid.

46 - 47 (cancel).

48 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with the administration of allergen desensitization.

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49 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with an NSAID.

50 (withdrawn). A method of treating an IgE-mediated disorder comprising administering to a patient in need thereof a therapeutically effective amount of the formulation of Claim 20 in combination with the administration of an NSAID.